K053000

NOV 2 1 2005

510(k) Summary

Statement This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter

Haemonetics Corporation
400 Wood Road
Braintree, MA. 02184-9114

Company Contact

Gabriel J. Muraca, Jr.
RA Project Manager
Haemonetics Corporation
400 Wood Road.
Braintree, MA. 02184-9114
781-356-9553

Device Name

Proprietary Name:

Cardiovascular Perioperative Autotransfusion System (cardioPAT™)

Common Name: Autotransfusion apparatus

Classification Name: Autotransfusion apparatus (CAC)

Predicate Device The predicate device is the Haemonetics® Cardiovascular Perioperative Autotransfusion System (cardioPAT™), previously cleared in K043127.

Device Description

The cardioPAT system is designed to provide perioperative autotransfusion for patients undergoing cardiovascular surgery. The system consists of an electromechanical device and a sterile single-use disposable set, which together collect and process red blood cells lost during or after surgery. It is designed to be used in the operating room to recycle blood lost during cardiovascular surgical procedures and in the recovery room to recycle blood lost after surgery, where the expected rate of processing of salvaged blood and fluid aspirated from the surgical site is less than or equal to two liters per hour. It is a small portable system which mounts on an IV pole.

Indications for Use

The Haemonetics® Cardiovascular Perioperative Autotransfusion System (cardioPAT™) is indicated for use to salvage red blood cells from blood lost intraoperatively and postoperatively during cardiovascular surgical procedures, where the expected rate of processing of salvaged blood and fluid aspirated from the surgical site is less than or equal to two liters per hour.

Autotransfusion is indicated for patients who meet at least one of the following criteria:

- The patient is expected to lose sufficient blood in the perioperative period, so as to require red blood cell transfusion, and autotransfusion will likely reduce or eliminate the need for allogeneic blood transfusion.
- Religious beliefs cause the patient to refuse allogeneic transfusion, but accept autologous transfusion.
- Compatible allogeneic blood is not available.
- The patient is unable to donate sufficient quantities of autologous blood prior to surgery to adequately cover the anticipated transfusion requirement.
- The patient or physician prefers perioperative autotransfusion rather than preoperative autologous donation or transfusion of allogeneic blood.

Performance

The quality of salvaged red blood cells returned to the donor during autotransfusion procedures with both the current cardioPAT and modified cardioPAT system is acceptable with respect to measured markers.

The following table is a summary from testing that shows the mean percent washout and the mean percent red blood cell recovery for pools of different hematocrit blood that were processed under simulated use conditions by the cardioPAT system.

Table 1: Data Summary for cardioPAT*

	Mean Washout			Mean Red Blood Cell Recovery
Hematocrit	Supernate Heparin (%)	Supernate Albumin (%)	Supernate Hemoglobin (%)	(%)
5%	99.88	99.90	99.38	77.83
15%	99.68	99.80	98.18	88.77
40%	97.19	97.67	94.37	91.00
Mean	98.9	99.1	97.3	85.9

*From TP- & TR-DIS-02028

Substantial Equivalence

The substantial equivalence of the cardioPAT System is substantiated by its similarities in intended use, technological characteristics, and performance to the previously marketed cardioPAT system. Fluid path materials and components in the modified and currently available disposable sets are identical.

Gabriel J. Muraca, Jr.

Date 10/24/05

Gabriel J. Muraca, Jr.
Regulatory Affairs Project Manager
HAEMONETICS CORPORATION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1 2005

Haemonetics Corporation
c/o Mr. Gabriel J. Muraca Jr.
Regulatory Affairs Project Manager
400 Wood Road
Braintree, MA 02184-9114

Re: K053000
Cardiovascular Perioperative Autotransfusion System (cardioPAT™)
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II (Two)
Product Code: CAC
Dated: October 24, 2005
Received: October 25, 2005

Dear Mr. Muraca:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053000

Device Name:

Haemonetics® Cardiovascular Perioperative Autotransfusion System (cardioPAT™)

Indications for Use:

The Haemonetics® Cardiovascular Perioperative Autotransfusion System (cardioPAT™) is indicated for use to salvage red blood cells from blood lost intraoperatively and postoperatively during cardiovascular surgical procedures, where the expected rate of processing of salvaged blood and fluid aspirated from the surgical site is less than or equal to two liters per hour.

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Prescription Use X and/or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kochner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K053000